SEP 19 1997

K972651

510(k) Summary

Influence, Inc.'s *IN-SLING*™

**** For Release Upon Request Only ****

Submitter's Name:

Influence, Inc.
601 Montgomery Street, Suite 845
San Francisco, California 94111

Contact Person:

Peter A. Bick, M.D.
President and CEO
Influence, Inc.
601 Montgomery Street, Suite 845
San Francisco, California 94111
Telephone: 415-421-5600 Fax: 415-421-5622

Date Prepared:

July 11, 1997

Trade Name:

IN-SLING™

Classification Name:

Mesh, Surgical, Polimeric

Classification:

The FDA has classified surgical mesh as a class II device (product code 79 FTL) and it is reviewed by the Plastic and Reconstructive Surgery Devices Branch.

Predicate Devices:

- Surgical Fabrics' *ProteGen*™ (K963226)
- Vascutek's *Gelseal*™ (K963611)

Performance Standards:

No performance standards applicable to surgical mesh have been established by the FDA.

Indication for Use:

The *IN-SLING*™ is intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence

Device Description:

The *IN-SLING*™ is a gelatin-sealed, knitted polyester patch fabric intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence.

Technological Characteristics and Substantial Equivalence:

The *IN-SLING*™ is identical to the *Vascutek Gelseal*™ in terms of materials, manufacturing, processing, packaging and sterilization. The only difference between the *IN-SLING* and the *Vascutek Gelseal*™ is in the size and shape of the fabric.

The *IN-SLING* is substantially equivalence to Surgical Fabrics' *ProteGen*™ in terms of intended use and labeling. Like the *ProteGen*™ is used with the *Vesica System* as a sling in sling procedures, the *IN-SLING*™ is used as a sling with Influence's transvaginal surgical systems (*In-Fast* and *In-Tac*) in sling procedures for the treatment of urinary incontinence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Peter A. Bick, M.D.
President and CEO
Influence, Inc.
601 Montgomery Street, Suite 845
San Francisco, California 94111

SEP 19 1997

Re: K972651
Trade Name: *IN-SLING*™
Regulatory Class: II
Product Code: FTL
Dated: July 14, 1997
Received: July 14, 1997

Dear Dr. Bick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements , as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972651

Device Name: IN-SLING

Indications For Use:

IN-SLING is intended to be used as a sling in transvaginal sling procedures for the treatment of urinary stress incontinence.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972651

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)